

POLICY AND COMMUNICATIONS BULLETIN

THE CLINICAL CENTER

Medical Administrative Series

M94-8 (rev.)

18 October 2000

MANUAL TRANSMITTAL SHEET

SUBJECT: "Per Protocol" Orders in the Clinical Center

1. Explanation of Material Transmitted: This issuance updates the policy of the Medical Executive Committee regarding the ability of members of the Research Staff, among others, to initiate this particular type of standing order at the Clinical Center. The policy was reviewed by the Medical Executive Committee on 17 October 2000 and approved with no changes.
2. Material Superseded: MAS No. M94-8 (rev.), dated 1 July 1997
3. Filing Instructions: Medical Records Section

Remove: No. M94-8 (rev.), dated 1 July 1997

Insert: No. M94-8 (rev.), dated 18 October 2000

DISTRIBUTION

Physicians, Dentists and Other Practitioners Participating in
Patient Care

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SUBJECT: "Per Protocol" Orders at the Clinical Center

PURPOSE

To define the term "Per Protocol" as it applies to medical orders at the Clinical Center (CC) and to identify those who may initiate such orders.

DEFINITIONS

A Standing Order, as defined in Medical Administrative Series Number M86-2, is a predetermined order generated by an authorized prescriber. Standing orders direct the execution of specific activities as a part of a diagnostic, therapeutic, and/or research regimen repeatedly performed over time.

A Per Protocol Order is a type of standing order that permits members of the Adjunct, Research, or Nursing Staff to perform specific, predetermined activities for which they are qualified. Such orders are predefined and authored by a member of the Senior Medical Staff. Such orders allow a member of the Adjunct, Research, or Nursing Staff to act as an agent regarding these orders in order to carry out certain procedures or activities required by specific protocol(s).

POLICY

1. As a function of their routine duties, it may be necessary for a member of the Adjunct, Research, or Nursing Staff to enter protocol-specific medical orders into the automated medical information system (MIS). Such orders shall be selected from a

predetermined set of standing orders that pertain to a specific research protocol and are called a "Per Protocol Order Set."

2. Each Per Protocol Order Set must be developed and authored only by a member of the Senior Medical Staff. The Per Protocol Order Set specifies the protocol and each order as it is to be entered in the MIS. In addition, the order set must identify that member of the Adjunct, Research, or Nursing Staff authorized to act as agent for the author and the length of time the person is so authorized (no longer than one year).
3. Each Per Protocol Order Set is to be entered on a manual Doctor's Order Sheet (SF-508), which is to be signed and dated by the author. Separate order sheets must be developed and signed for each Protocol Order Set. The completed order set is to be delivered to the Information Systems Department (ISD), which is responsible for developing appropriate computer screens for selection and entry of the order set. Each order set is to receive a unique identifying number from the ISD. The Manual Per Protocol Order Sets shall be maintained in the ISD from initial approval through seven years following discontinuance.
4. Medical record documentation of Per Protocol Orders shall include each specific order, the authorized agent, and the author of the Protocol Order Set. In addition, the text "per protocol order signature on file" is to be entered with each order. Per Protocol Orders do not require countersignature.
5. Each order set must be reviewed and reauthorized annually by the author. The review shall be coordinated by staff of the ISD, who are responsible for requesting review, revision, renewal, or termination of the order set. Orders may not be issued from a Per Protocol Order Set until it has been reviewed and implemented on MIS by staff of the ISD.
6. In order for a Per Protocol Order Set to be activated for a specific patient on MIS, an order must be entered into MIS by a member of the Junior or Senior Medical staff. This establishes that the author has requested execution of orders from a specific Per Protocol Order Set for that patient. The order should follow the form: "Initiate Per Protocol Order Set Number ####." Electronic signature in MIS denotes

authorization. A verbal order may not be issued to request activation of a Protocol Order Set.